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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,867	06/05/2006	Michael Horstmann	RO4244US (#90568)	3928

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EXAMINER	
MATTER, KRISTEN CLARETTE	
ART UNIT	PAPER NUMBER
3771	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,867	HORSTMANN ET AL.	
	Examiner	Art Unit	
	KRISTEN C. MATTER	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8,9 and 12-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,9 and 12-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

This Action is in response to the amendment filed 3/14/2011. Claim 1has been amended, and no claims have been cancelled or added. Thus, claims 1-6, 8, 9, and 12-30 are currently pending in the instant application.

Response to Arguments

Applicant's arguments filed 3/14/2011 have been fully considered but they are not persuasive.

In response to applicant's argument that Honeycutt needs modified so much to arrive at the instant invention that any modification cannot be considered obvious (page 13 of remarks), examiner respectfully disagrees. The main thing being modified in Honeycutt is how the compositions are being stored/released. Storing nicotine/basic active ingredients and volatile acids for slow release by dissolving/dispersing them in a polymer matrix is well known as discussed in the instant rejection. Using a well known composition storage/release means in a well known device leads to predictable results that do not patentably distinguish an invention over the prior art. Furthermore, modification of mere dimensions does not patentably distinguish an invention over the prior art. As discussed in the rejection, "puffs" of 1-10 seconds are common for smoking simulators, as is a release of 5-250 micrograms of nicotine per puff. Precisely how much is released depends on how much composition is dispersed in the matrix, the dimensions of the device/air paths, the strength of the user's inhalation, etc., all of which are either out of the designer's control (i.e., user's discretion/ability) or a mere design consideration involving changing a dimension to optimize the amount of composition released per puff to

ensure that a user gets an effective amount of composition per use (i.e., enough nicotine to feel the effects but not so much as to poison the user, for example). This is considered especially obvious when using the well known structure of slow release compositions of preparations dispersed in polymer matrices in the Honeycutt device (i.e., since the structures are the same, the amount released would behave in the same manner).

In response to applicant's arguments against the references individually Honeycutt on page 12, Baker and Martyn on page 14), one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Here, examiner does not argue that a single reference teaches all of the limitations of the instant invention, which is why an obviousness rejection was made instead of an anticipatory rejection. However, one of ordinary skill in the art, upon seeing the cited references, would find it obvious to arrive at the instant invention. Baker was cited merely to show that nicotine bases and volatile acids can be stored and released for therapy from polymethyl methacrylate polymer matrices. Baker does not need to specifically teach inhalation therapy because Honeycutt teaches the release of these compositions into the airways for therapy and Martyn teaches that technologies used for transdermal therapy are interchangeable with those used for inhalation therapy. Likewise, the fact that Martyn teaches different compounds and/or materials for the matrix are not relevant to the instant invention since the materials and compounds are taught by Honeycutt and/or Baker. Honeycutt teaches the outline of the device including the claimed flow apertures, Baker teaches that it is well known to disperse nicotine bases and volatile acids in polymer matrices for slow release delivery, Martyn teaches that it

would have been obvious to look at both transdermal and inhalation techniques when storing slow release compositions, and Ek discloses that the claimed release amounts and puffs are well known in the art. Therefore, absent a showing of unexpected results from such a modification, examiner contends that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have replaced the composition storage/release means of Honeycutt with the preparations dispersed in a polymer matrix as taught by Baker and to have used that for inhalation therapy as taught by Martyn by modifying the dimensions of the device to ensure an effective amount of drug delivery as taught by Ek.

In response to applicant's comment on page 15 that there is nothing in Baker that discloses that a volatile acid can be present separately in a polymer composition, examiner notes that there is also nothing in the art suggesting that it cannot be stored separately, and there is nothing on the record indicating an unexpected result occurs from storing the volatile acid separately. It appears that since it can be stored with the nicotine base, that the volatile acid would be able to be stored separately or with other compounds as well. Examiner also notes that there is nothing in the claims actually requiring that the volatile acid be stored separately (i.e., the second preparation just need contain at least one volatile acid, so if it also contained nicotine base or any other compound for that matter, this would still read on the claim).

Regarding applicant's argument on page 15 and the Ek reference, again examiner notes that the specifics of the inhaler of Ek are not relevant to the instant rejection. Ek was cited merely as teaching that that claimed puffs and release rates were well known as effective therapy amounts at the time the invention was made. One of ordinary skill in the art would know how to modify the dimensions of the modified Honeycutt device to ensure an optimal amount of

compound was released per puff, for an average inhalation puff. As discussed above, a mere change in dimension or optimization of a value within a working range does not patentably distinguish an invention over the prior art. Since the structure of the modified Honeycutt device is the same as the instant invention, the release rates would behave in the same manner as well.

Claim Objections

Claims 1, 6, and 26 are objected to because of the following informalities: In claim 1, lines 13-14, claim 6, line 1, and claim 26, line 1, "in use" language should be added to make it clear that these limitations are only occurring while the device is in use and to avoid possible claiming on non-statutory subject matter. Also, in claim 1, line 14, “reaches” should be changed to --reaching-- to fix a grammatical mistake.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 8, 9, and 12-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 21, the term "the polymer matrix" is confusing because there is more than one polymer matrix claimed, making it unclear which matrix is being referred to here.

Claims 2-6, 8, 9, and 12-20 are rejected by virtue of their dependence on claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1, 2, 5, 6, 8, 12, 14, 22, 23, 26, and 30 are rejected under 35 U.S.C. 103(a) as obvious over Honeycutt (4,765,348) in view of Baker et al. (US 5,721,257, herein referred to as "Baker"), Martyn et al. (WO 2003/053413, herein referred to as "Martyn"), and Ek et al. (US 2005/0053665, herein referred to as "Ek").

Regarding claims 1, 2, 5, 8, 12, 14, 22, 23, 26, and 30, Honeycutt discloses a device for administration of nicotine to the human body by inhalation (column 1, lines 37-45) for the purpose of being a non-combustible simulated cigarette (column 1, 8-10), wherein the device comprises a first preparation (18) containing a free base of nicotine (column 1, lines 45-46) which is contained by absorption in a polytetrafluoroethylene element (column 3, lines 11-18), and a second preparation (20) containing a volatile acid (column 1, lines 46-52), such as acetic acid (column 2, line 39) which is separated from the first preparation (18) by an impermeable partition (24) (column 2, lines 48-49). The device contains a first air inlet, located to the right of section 18 in figure 3, directing an inhaled airstream into an oblong air supply channel, around #18 in figure 3, a second air inlet, located to the right of section 20 in figure 3, directing an inhaled airstream into an oblong air supply channel, around #20 in figure 3, a common flow path (22) where the two airstreams from the separate sections combine simultaneously due to

inhalation and an outlet aperture (16) where the common flow path leads to (column 2, lines 60-69), all of which have a conduit cross-section.

Honeycutt lacks the first and additional preparations comprising a polymer matrix with the agent and acid being contained in a dissolved or dispersed form. However, Baker discloses a smoking cessation device with nicotine and/or additive salts including acetic acid (column 7, lines 20-25) dispersed (column 8, lines 20-35) within a PMMA polymer matrix (column 10, lines 5-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have dispersed the nicotine and acid of Honeycutt in polymer matrices as taught by Baker in order to safely deliver a slow release of nicotine to a user for smoking cessation. Examiner notes that Baker teaches the device for transdermal delivery. However, Martyn teaches a similar slow release composition in which therapeutic agents (including acids) are dispersed in a polymer matrix (abstract) and can be used in either transdermal or inhalation therapy (see claims 10 and 11). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the dispersed form of preparations taught by Baker for inhalation therapy in the modified Honeycutt/Baker device since at the time of the invention it was well known that such compositions were interchangeable as taught by Martyn. Such a modification appears to involve the mere use of one well known nicotine storage/release means for another to yield predictable results that do not patentably distinguish an invention over the prior art. Furthermore, there is nothing structurally in Honeycutt preventing the preparations from being stored/released using polymer matrices as taught by Baker (or any similar well known means for that matter).

Honeycutt is also silent as to the exact flow rates and nicotine release. However, Ek discloses that during inhalation therapy, depending on flow resistance, etc. an average amount of 8-10 micrograms of nicotine is released per puff from nicotine contained within cellulose matrices (paragraph 106). Therefore, absent a critical teaching and/or showing of unexpected results from such flow rates, examiner contends that puffs from 1-10 seconds at 01-1 L/min are well known as common for smokers and that with such puffs, release of 5-250 micrograms of the nicotine would have been obvious because such amounts are common in the art at taught by Ek for delivering an effective and safe amount of nicotine to a user. The exact amount would depend on design considerations such as how much nicotine was dispersed in the matrix, the puff strength, flow properties of the device, etc., which would depend on user capabilities and mere changes in dimension.

Likewise, Honeycutt is silent as to particle size and negative pressure differential. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device with appropriate size elements to create airflows and chemical balances necessary to operate the device successfully (column 3, lines 1-10), since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. See In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Additionally, a mere change in dimension does not patentably distinguish an invention over the prior art and particles of less than 10 microns are well known as appropriate for allowing delivery of particles to a user's airways.

Regarding claim 6, Honeycutt discloses the chemical balance between volatized nicotine and acid can be controlled (column 3, lines 1-10), but does not disclose the exact ratio of the

chemical balance. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made that during inhalation a ratio of equimolar quantities of the nicotine and acid could be released in order to provide the advantage of giving the vapor a neutral pH.

Claims 3, 4, 9, 24, 25, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt, Baker, Martyn, and Ek as applied to claims 1, 2, 5, 6, 8, 12, 14, 22, 23, 26, and 30 above, and further in view of Ray (4,284,089).

Regarding claims 3, 4, 9, 24, 25 and 27, Honeycutt does not disclose the preparations containing a solvent suitable for inhalation. However, Ray teaches a preparation containing water as a solvent as well as menthol dissolved in ethanol as a flavoring (column 4, lines 23-28; column 7, lines 14-22). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the inhaler of Honeycutt with solvents as taught by Ray in order to provide the advantages of adjusting the humidity of vapors released and providing flavor to the vapors.

Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt, Baker, Martyn, and Ek as applied to claims 1, 2, 5, 6, 8, 12, 14, 22, 23, 26, and 30 above, and further in view of Turner (5,400,808).

Regarding claims 28 and 29, Honeycutt discloses the device having an impermeable part (24) (column 2, lines 48-49) as well as discloses that the device can be made of any material (column 2, lines 11-13), but does not disclose a definite composition of the whole device. However, Turner teaches a nicotine impermeable container constructed of aluminum foil coated

with a copolymer of acrylonitrile and methyl acrylate (column 2, lines 36-41). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the inhaler of Honeycutt with a material as taught by Turner in order to provide the advantage a longer shelf life of the contents of the inhaler. In addition, having the entire device be made out of the impermeable material of impermeable partition (24) and for this material to be a polyester material coated with a copolymer would help ensure all the composition released is directed through the outlet to the airway. See also In re Leshin, 125 USPQ 416, ion which is was held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt, Baker, Martyn, and Ek as applied to claims 1, 2, 5, 6, 8, 12, 14, 22, 23, 26, and 30 above, and further in view of Ferre (726,037).

Regarding claim 13, Honeycutt does not disclose a peelable protective layer to form compartments containing the active agent and acid protecting them from ambient air. However, Ferre teaches an inhaler with separate impermeable (lines 53-54) compartments (a, c) that have orifices (f) that can be opened or closed (line 70). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the inhaler of Honeycutt with a sealable compartments as taught by Ferre, and for the compartments to be sealable with a peelable layer in order to provide the advantage of a longer shelf life of the contents of the compartments as well as an inexpensive, easy disposable sealing means as is well known in the art.

Claims 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt, Baker, Martyn, and Ek as applied to claims 1, 2, 5, 6, 8, 12, 14, 22, 23, 26, and 30 above, and further in view of Kallstrand (5,660,169).

Regarding claims 15-21, Honeycutt discloses the claimed structure of the invention needed to read on claims 15-21, including the oblong recesses as discussed above in the rejection of claim 1, but lacks the parts being formed by deep-drawing. Kallstrand discloses an inhaler device with an upper (1) and bottom part (2), containing a compartment with a peelable seal (figs. 3a-c), formed by deep-drawing (column 2, lines 11-14). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to provide the inhaler of Honeycutt with deep-drawn components as taught by Kallstrand in order to provide the advantage of an inexpensive way to manufacture the device. Furthermore, there is nothing structurally preventing the device from being manufactured using any well known technique and it appears as though the modified Honeycutt device would work equally well if produced by deep-drawing. such a modification appears to involve the mere use of a well known manufacturing means in a well known device to yield predictable results that do not patentably distinguish an invention over the prior art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN C. MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kristen C. Matter/
Examiner, Art Unit 3771